



BILLING CODE: 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-18-0200; Docket No. CDC-2018-0030]

Proposed Data Collections Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC),
Department of Health and Human Services (HHS)

ACTION: Notice with comment period

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled "Coal Workers' Health Surveillance Program (CWHSP). The CWHSP is a congressionally-mandated medical examination program for monitoring the health of coal miners and was originally established under the Federal Coal Mine Health and Safety Act of 1969 with all subsequent amendments (the Act).

DATES: CDC must receive written comments on or before **[INSERT DATE 60 DAYS AFTER PUBLICATION DATE IN THE FEDERAL REGISTER]**.

ADDRESSES: You may submit comments, identified by Docket No. CDC-2018-0030 by any of the following methods:

- Federal eRulemaking Portal: Regulations.gov. Follow the instructions for submitting comments.
- Mail: Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to Regulations.gov.

Please note: Submit all Federal comments through the Federal eRulemaking portal (regulations.gov) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329; phone: 404-639-7570; E-mail: omb@cdc.gov.

SUPPLEMENTARY INFORMATION:

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of

information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected; and
4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of

information technology, e.g., permitting electronic submissions of responses.

5. Assess information collection costs.

Proposed Project

Coal Workers' Health Surveillance Program (CWHSP), OMB Number 0920-0020, expires 06/30/2018 - Extension- for National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

NIOSH would like to extend the Coal Workers' Health Surveillance Program (CWHSP) data collection project. This request incorporates all components of the CWHSP. Those components includes Coal Workers' X-ray Surveillance Program (CWXSP), B Reader Program, Enhanced Coal Workers' Health Surveillance Program (ECWHSP), Expanded Coal Workers' Health Surveillance Program, and National Coal Workers' Autopsy Study (NCWAS).

The CWHSP is a congressionally mandated medical examination program for monitoring the health of coal miners and was originally established under the Federal Coal Mine Health and Safety Act of 1969 with all subsequent amendments (the Act). The Act provides the regulatory authority for the administration of the CWHSP. This Program, which operates in accordance with 42 CFR Part 37, is useful in providing information for protecting

the health of and also in documenting trends and patterns in the prevalence of coal workers' pneumoconiosis ('black lung' disease) among miners employed in U.S. coal mines. The total estimated annualized burden hours of 20,281 is based on the following collection instruments:

- Coal Mine Operator Plan (2.10) and Coal Contractor Plan (2.18) - Under 42 CFR Part 37, every coal operator and coal contractor in the U.S. must submit a plan approximately every 4 years, providing information on how they plan to notify their miners of the opportunity to obtain the medical examination. Completion of this form with all requested information (including a roster of current employees) takes approximately 30 minutes.
- Radiographic Facility Certification Document (2.11) - X-ray facilities seeking NIOSH approval to provide miner radiographs under the CWHSP must complete an approval packet including this form that requires approximately 30 minutes for completion.
- Miner Identification Document (2.9) - Miners who elect to participate in the CWHSP must fill out this document, which requires approximately 20 minutes. This document records demographic and occupational history, as well as

information required under the regulations in relation to the examinations.

- Chest Radiograph Classification Form (2.8) - NIOSH utilizes a radiographic classification system developed by the International Labour Office (ILO) in the determination of pneumoconiosis among coal miners. Physicians (B Readers) fill out this form regarding their interpretations of the radiographs (each image has at least two separate interpretations, and approximately 7% of the images require additional interpretations). Based on prior practice it takes the physician approximately three minutes per form.
- Physician Application for Certification (2.12) - Physicians taking the B Reader examination are asked to complete this registration form, which provides demographic information as well as information regarding their medical practices. It typically takes the physician about 10 minutes to complete this form.
- Guidelines for Spirometry in the ECWHSP Mobile (Internal use, no form number assigned) - Miners (both active and former) participating in the ECWHSP component of the Program are offered a spirometry test. This form is administered by a NIOSH employee (or contractor) in the ECWHSP Mobile Unit during the initial intake process and

takes approximately five minutes to complete. This information is required to make sure that the spirometry test can be done safely and that the miner is physically capable of performing the spirometry maneuvers.

- Spirometry Facility Certification Document (2.14) - This form is analogous to the Radiographic Facility Certification Document (2.11) and records the spirometry facility equipment/staffing information. Spirometry facilities seeking NIOSH approval to provide miner spirometry testing under the CWHSP must complete an approval packet, which includes this form. It is estimated that it will take approximately 30 minutes for this form to be completed at the facility.
- Respiratory Assessment Form (2.13) - This form is designed to assess respiratory symptoms and certain medical conditions and risk factors. It is estimated that it will take approximately five minutes for this form to be administered to the miner by an employee at the facility.
- Spirometry Results Notification Form (2.15) - This form is used to: collect information that will allow NIOSH to identify the miner in order to provide notification of the spirometry test results; assure that the test can be done safely; record certain factors that can affect test

results; provide documentation that the required components of the spirometry examination have been transmitted to NIOSH for processing; and conduct quality assurance audits and interpretation of results. It is estimated that it will take the facility approximately 20 minutes to complete this form.

- Pathologist Invoice - Under the NCWAS, the invoice submitted by the pathologist must contain a statement that the pathologist is not receiving any other compensation for the autopsy. Each participating pathologist may use their individual invoice as long as this statement is added. It is estimated that only 5 minutes is required for the pathologist to add this statement to the standard invoice that they routinely use.
- Pathologist Report - Under the NCWAS, the pathologist must submit information found at autopsy, slides, blocks of tissue, and a final diagnosis indicating presence or absence of pneumoconiosis. The format of the autopsy reports is variable depending on the pathologist conducting the autopsy. Since an autopsy report is routinely completed by a pathologist, the only additional burden is the specific request for a clinical abstract of terminal illness and final diagnosis relating to pneumoconiosis.

Therefore, only 5 minutes of additional burden is estimated for the pathologist's report.

- Consent, Release and History Form (2.6) - This form documents written authorization from the next-of-kin to perform an autopsy on the deceased miner. A minimum of essential information is collected regarding the deceased miner including an occupational history and a smoking history. From experience, it is estimated that 15 minutes is required for the next-of-kin to complete this form.

There are no costs to respondents other than their time.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)
Coal Mine Operator	2.10	388	1	30/60	194
Coal Mine Contractor	2.18	575	1	30/60	288
X-ray Facility Supervisor	2.11	40	1	30/60	20
Coal Miner	2.9	14,560	1	20/60	4,854
Coal Miner	No form	14,560	1	15/60	3,640
B Reader Physician	2.8	10	3014	3/60	1,507
Physicians taking the B Reader Examination	2.12	100	1	10/60	17
Spirometry Facility Supervisor	2.14	100	1	30/60	50

Spirometry Facility Employee	2.13	14,560	1	5/60	1,214
Spirometry Technician	2.15	14,560	1	20/60	4,854
Coal Miner	No form	14,560	1	15/60	3,640
Pathologist	Invoice --No standard form	1	1	5/60	1
Pathologist	Pathology Report -- No standard form	1	1	5/60	1
Next-of-kin for deceased miner	2.6	1	1	15/60	1
Total					20,281

Leroy A. Richardson,

Chief,

Information Collection Review Office,

Office of Scientific Integrity,

Office of the Associate Director for Science,

Office of the Director,

Centers for Disease Control and Prevention.

[FR Doc. 2018-07563 Filed: 4/11/2018 8:45 am; Publication Date: 4/12/2018]